REMARKS

This Amendment and Response responds to the Final Office Action dated January 17, 2006, but is presented in Appeal Brief format. No claims are amended, cancelled, or added. As a result, claims 1-47 are pending in this patent application.

1. Real Party In Interest

The real party in interest of the above-captioned patent application is the Assignee, Cardiac Pacemakers, Inc.

2. Related Appeals and Interferences

There are no other appeals or interferences known to Appellant that will have a bearing on the Board's decision in an appeal of this matter.

3. Status of the Claims

Claims 1-47 are currently pending in this patent application. A Final Office Action was mailed on January 17, 2006. Claims 20-27 have been allowed. Claims 1-19 and 28-47 stand finally rejected, and their rejection is the subject of the appeal of this matter.

4. Status of Amendments

The Final Office Action indicated that Appellant's previous claim amendment after final rejection has been entered. Accordingly, all claim amendments have now been entered into the record.

5. Summary of Claimed Subject Matter

Independent apparatus claim 1 relates to an implantable far-field telemetry module (*see, e.g.*, Application, Fig. 2 at 130) including at least one data interface connector (Fig. 7 at 433C) adapted to connect the telemetry module 130 to an implantable medical device (Figs. 2 & 7 at 105). This permits wired communication of data from the implantable medical device 105 to the telemetry module 130. (*See* Application at page 18, lines 28-30.) The telemetry module 130, in

turn, provides wireless communication of the data to an external device. (*See* Application at page 9, line 22 through page 10, line 1.) The interface connector 433C is a user-attachable connector or a detachable connector. (*See, e.g.,* Application at page 10, lines 14-26.)

Independent method claim 28 relates to connecting a user-attachable or detachable implantable far-field telemetry module 130 to an implantable medical device 105 to provide "wired" transmission of data from the implantable medical device to the telemetry module. (*See* Application at page 18, lines 28-30.) The telemetry module 130, in turn, is used to provide far-field wireless telemetry of the data from the implantable medical device. (*See* Application at page 9, line 22 through page 10, line 1.)

Independent method claim 37 relates to connecting a user-attachable or detachable implantable far-field telemetry module 130 to an implantable medical device. Far-field telemetry is provided for the implantable medical device 105 using the telemetry module 130. The far-field telemetry includes receiving, via "wired" communication using an electrical conductor, a first data stream from the implantable medical device 130. (*See* Application at page 18, lines 28-30.) A first radio-frequency RF carrier suitable for far-field data transmission from within a body is generated using the telemetry module 105. (*See* Application at page 9, line 22 through page 10, line 1.) The first RF carrier is modulated to be representative of the first data stream. (*See id.*) The modulated first RF carrier is wirelessly transmitted. (*See id.*)

This summary is provided for the convenience of the Board of Appeals and Patent Interferences. It is not to be used to limit the scope of the claims.

6. Grounds for Rejection to Be Reviewed on Appeal

1) Was a *prima facie* case of anticipation under 35 U.S.C. § 102(e) properly made with respect to claims 1-3, 5-16, 19, 28-33, 35-44 and 46 using Lee et al. (U.S. Patent No. 6,920,360)?

7. Argument

A) The Applicable Law

Anticipation under 35 U.S.C. § 102 requires the disclosure in a single prior art reference of each element of the claim under consideration. *See Verdegaal Bros. V. Union Oil Co. of*

California, 814 F.2d 628, 631, 2 USPQ 2d 1051, 1053 (Fed. Cir. 1987). It is not enough, however, that the prior art reference discloses all the claimed elements in isolation. Rather, "[a]nticipation requires the presence in a single prior reference disclosure of each and every element of the claimed invention, *arranged as in the claim.*" *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 USPQ 481, 485 (Fed. Cir. 1984) (citing *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983)) (emphasis added). "The *identical invention* must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989); MPEP § 2131 (emphasis added). In interpreting the claims it is widely recognized that a patentee is free to be his own lexicographer. *See, e.g., Autogiro Co. of America v. United States*, 384 F.2d 391,397 (Ct. Cl. 1967). However, unless a special definition is clearly stated in the patent specification or prosecution history, claim terms are to be given their ordinary and customary meaning in the field of the invention. *See Vitronics*, 90 F.3d at 1582, 39 U.S.P.Q.2d at 1576.

The Examiner also has the burden under 35 U.S.C. § 103 to establish a *prima facie* case of obviousness. *In re Fine*, 837 F.2d 1071, 1074, 5 U.S.P.Q.2d (BNA) 1596, 1598 (Fed. Cir. 1988). In combining prior art references to construct a *prima facie* case, the Examiner must show some objective teaching in the prior art or some knowledge generally available to one of ordinary skill in the art that would lead an individual to combine the relevant teaching of the references. *Id.* The M.P.E.P. contains explicit direction to the Examiner that agrees with the *In re Fine* court:

> In order for the Examiner to establish a *prima facie* case of obviousness, three base criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *M.P.E.P.* § 2142 (citing *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d (BNA) 1438 (Fed. Cir. 1991)).

An invention can be obvious even though the suggestion to combine prior art teachings is not found in a specific reference. *In re Oetiker*, 977 F.2d 1443, 24 U.S.P.Q.2d (BNA) 1443 (Fed. Cir. 1992). However, while it is not necessary that the cited references or prior art specifically suggest making the combination, there must be some teaching somewhere which provides the suggestion or motivation to combine prior art teachings and applies that combination to solve the same or similar problem which the claimed invention addresses. One of ordinary skill in the art will be presumed to know of any such teaching. (See, e.g., *In re Nilssen*, 851 F.2d 1401, 1403, 7 U.S.P.Q.2d 1500, 1502 (Fed. Cir. 1988) and *In re Wood*, 599 F.2d 1032, 1037, 202 U.S.P.Q. 171, 174 (C.C.P.A. 1979)). However, the level of skill is not that of the person who is an innovator but rather that of the person who follows the conventional wisdom in the art. *Standard Oil Co. v. American Cyanamid Co.*, 774 F.2d 448, 474, 227 U.S.P.Q. 293, 298 (Fed. Cir. 1985). The requirement of a suggestion or motivation to combine references in a *prima facie* case of obviousness is emphasized in the Federal Circuit opinion, *In re Sang Su Lee*, 277 F.3d 1338; 61 U.S.P.Q.2D 1430 (Fed. Cir. 2002), which notes that the motivation must be supported by evidence in the record.

The test for obviousness under § 103 must take into consideration the invention as a whole; that is, one must consider the particular problem solved by the combination of elements that define the invention. *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1143, 227 U.S.P.Q. 543, 551 (Fed. Cir. 1985). References must be considered in their entirety, including parts that teach away from the claims. See MPEP § 2141.02. The fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 16 USPQ2d 1430 (Fed. Cir. 1990); M.P.E.P. § 2143.01.

B) The Reference

Lee (U.S. Patent No. 6,920,360): describes an implantable medical device (IMD) 112 that communicates with an external routing instrument 118, which in turn communicates with a large scale external computer 116 via a network 230 or a direct connection 232. An implantable telemetry device 120 is shown as being part of the IMD 112 in FIG. 2 of Lee, however, the implantable telemetry device 120 appears to be shown as ancillary to the IMD 112 in FIG. 1 of Lee. Lee barely mentions the implantable telemetry device 120. Lee merely states:

> In an alternate embodiment of the subject invention, multiple IMDs deployed in a single patient are all linked to a single telemetry device implanted in a patient. This telemetry device may be separate from or incorporated into one of the IMDs deployed in a patient. Returning to the single IMD embodiment depicted in FIG. 1, IMD 112 is equipped with or linked to a transmission and receiving device such as a radio frequency telemetry device 120, also implanted in patient 114.

(Lee at col. 8, lines 10-18.) Nothing in Lee discloses that the implantable telemetry device 120 of Lee is detachable, either expressly or inherently.

C. Discussion of the Rejection

As an initial note, Appellant does not admit that Lee et al. is prior art. Appellant reserves the right to swear behind Lee et al. at a later date. Moreover, because Lee et al. fails to disclose the identical invention as claimed, Appellant respectfully traverses this rejection as discussed below.

Appellant cannot find any disclosure in Lee of an implantable medical device (IMD) with an implantable telemetry module that is user-attachable or detachable. The Office Action admitted that Lee does not teach a detachable telemetry module. (*See* Office Action at 2.) Instead, the Office Action asserts that "The Lee et al. telemetry system is inherently detachable." (Office Action at 2.) The Office Action failed to provide any reasoning for this assertion of inherency, and Appellant respectfully disagrees with this assertion. Appellant respectfully submits that the Office Action has not established a *prima facie* case of inherency because, as recited in MPEP § 2112, "In relying upon the theory of inherency, the examiner must provide basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art," citing Ex parte Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original).The Office Action only argued that "the Lee et al. telemetry system is inherently detachable," without providing any reasoning. Thus, the Office Action does not even assert that the allegedly inherent characteristic is necessary, let alone provide a basis in fact and/or technical reasoning. Appellant respectfully submits that a detachable telemetry module does not necessarily flow from Lee, which barely mentions the telemetry module 120 and is instead directed primarily toward a large-scale processing loop for implantable medical devices. Certainly, it is possible that Lee's implantable telemetry module 120 is permanently attached to the IMD 112 at the manufacturing

facility. In sum, it cannot be said that Lee's telemetry module 120 is necessarily detachable, which is required for a proper finding of inherency. To serve as an anticipation when a reference is silent about the asserted inherent characteristic, the gap in the reference may be filled with recourse to extrinsic evidence. But, such evidence must make clear that "the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." *Continental Can Co. v. Monsanto Co.*, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991). Applicant respectfully submits that the Examiner has not produced any extrinsic evidence to show that the detachable telemetry module recited or incorporated in the present claims is necessarily present in Lee.

Moreover, this claimed difference from Lee solves a distinct problem. Existing implantable medical devices with telemetry (including the device shown in Lee) typically are manufactured with the same type of telemetry circuit for all such devices of a particular model type. However, the present inventors have recognized that a particular patient's telemetry needs may differ from another patient's telemetry needs—even though both such patients would otherwise be suitable candidates for the same model of implantable medical device. (*See, e.g.*, Application at page 4, lines 5-8.) As an illustrative example, a first patient may live in a first country, which by its laws requires communication at a first frequency, and a second patient may live in a different second country, which by its laws requires communication at a different second frequency. The present user-attachable and detachable telemetry module would allow a clinician or other user to use a particular far-field telemetry module for a particular patient that is tuned or otherwise particularly adapted to best serve that patient's telemetry needs. The present claimed invention allows the user to mix-and-match far-field telemetry modules and implantable medical device models, thereby allowing greater flexibility in meeting a particular patient's needs.

Moreover, where geographic or political regions impose different telemetry requirements, as discussed above, allowing such a mix-and-match between implantable medical device models and user-detachable and attachable telemetry units advantageously makes global distribution of product an easier task for the manufacturer.

Furthermore, if one of the implantable medical device and the user-attachable and detachable remote far-field telemetry module were to fail, it could be replaced without replacing the other, resulting in cost-savings to the patient.

In sum, because all claimed elements are not shown in Lee, Appellant respectfully submits that no *prima facie* case of anticipation exists with respect to the present claims. Moreover, when the claimed invention is viewed as a whole, it provides distinct clinical advantages over Lee. Accordingly, Appellant respectfully requests reversal of the rejection of claims 1-19 and 28-47.

8. Summary

In summary, because Lee fails to disclose a detachable telemetry module, it cannot anticipate any of the present claims 1-47.

Therefore, Appellant respectfully requests reversal of all bases of rejection of all claims.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (612) 373-6951 to facilitate prosecution of this application and to avoid an appeal.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

WILLIAM R. MASS ET AL.

By their Representatives,

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. Box 2938
Minneapolis, MN 55402
(612) 373-6951

Date March 2, 2006

By S. Arora

Suneel Arora
Reg. No. 42,267

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Mail Stop AF, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 3 day of ~~February~~ March, 2006.

Paula Sucha

Name

Paula Sucha

Signature